

REMARKS

Status of the Claims.

Claims 1, 6-19, 23, and 45-69 are pending with entry of this amendment, no claims being cancelled and no claims being added herein. Claim 58 is amended herein. This amendment introduces no new matter. Support is found, for example, at page 3, line 3.

35 U.S.C. §102.

A) Tanner *et al.*

The rejection of claims 1, 6, 8, 10, 12, 14, 16, 18, 45, 46, 47-61, 63, 64, 68, and 69 under 35 U.S.C. §102(b) as allegedly anticipated by Tanner *et al.* (1994) *Cancer Res.* 54: 4257-4260 was maintained. . In particular, the Examiner alleges that because claim 1 utilizes "comprising" language and because the SEQ ID NOS:2010 and 12 are comprised within the 20q13 amplicon and thRMC20C001 hybridizes to the amplicon, the disclosure of Tanner *et al.* anticipates the claims. Applicants traverse.

In effect the Examiner argues that because of the comprising language, Applicants claimed nucleic acids could include RMC20C001 they are anticipated by Tanner *et al.* In effect, the Examiner improperly constructs the anticipation rejection backwards. This issue is not what additional sequences may comprise the presently claimed nucleic acid, but rather, what nucleic acids are to be found in the cited art.

The Examiner is respectfully reminded that anticipation requires that "all limitations of the claim are found in the reference, or 'fully met' by it." Kalman v Kimberly-Clark Corp., 218 USPQ 781, 789 (Fed. Cir. 1983).

Thus, to make a *prima facie* case of anticipation of the presently pending claims, the Examiner must find in Tanner *et al.*

An isolated nucleic acid molecule comprising a labeled polynucleotide sequence that hybridizes under stringent conditions to a sequence or to a complement of a sequence selected from the group consisting of SEQ. ID. No. 2, SEQ. ID. No.3, SEQ. ID. No.4, SEQ. ID. No.5, SEQ. ID. No.6, SEQ. ID. No.7, SEQ. ID. No.8, SEQ. ID. No.9, and SEQ. ID. No.10,

wherein said stringent conditions comprise a 0.02 molar salt concentration and a temperature of at least 60°.

The isolated nucleic acid sequence allegedly disclosed by Tanner *et al.* is the probe RMC20C001. As explained in the previous office action, RMC20C001 does not overlap the recited sequences. **Moreover, the fact that RMC20C001 hybridizes to some portion of the 20Q13 amplicon does not establish that RMC20C001 will hybridize under stringent conditions to the recited sequences which reside in a different portion of the amplicon..**

The cited art simply offers no disclosure of a sequence that "hybridizes under stringent conditions to a sequence or to a complement of a sequence selected from the group consisting of SEQ. ID. No. 2, SEQ. ID. No.3, SEQ. ID. No.4, SEQ. ID. No.5, SEQ. ID. No.6, SEQ. ID. No.7, SEQ. ID. No.8, SEQ. ID. No.9, and SEQ. ID. No.10" as required by claim 1.

Accordingly, the Examiner has failed to make her *prima facie* case, and the rejection of

B) New England Biolabs Catalog.

The rejection of claims 58-61 were under 35 U.S.C. §102(b) as allegedly anticipate by the New England Biolabs Catalog (1993-1994, page 91) was maintained. Applicants traverse.

Claim 58, as amended herein recites:

58. An isolated nucleic acid molecule comprising a polynucleotide sequence that hybridizes under stringent conditions **and forms a stable hybridization complex** to a sequence or to a complement of a sequence selected from the group consisting of SEQ. ID. NO. 2, SEQ. ID. NO.3, and SEQ ID NO: 12, wherein said stringent conditions comprise a 0.02 molar salt concentration and a temperature of at least 60°C.

The New England Biolabs reference simply discloses a random collection of 6-mer oligonucleotides. It is well accepted that at nucleic acid length decreases, stability of a hybridization complex formed therefrom also decreases. In the instant case, **6 mer oligonucleotides are extremely short and unlikely to form a stable hybridization complex (even with a perfect complement) under the stringent hybridization conditions recited in claim 58.**

The Examiner has offered no evidence whatsoever establishing that the primers allegedly disclosed in the New England Biolabs catalogue hybridize to the recited sequences under the

claimed conditions and form a stable hybridization complex. Lacking such evidence, the Examiner has simply failed to make her *prima facie* case. Accordingly, the rejection of claims 1, 6, 8, 10, 12, 14, 16, 18, 45, 46, 47-61, 63, 64, 68, and 69 under 35 U.S.C. §102(b) as on these grounds should be withdrawn.

Obviousness-type double patenting.

Claims 1, 6-19, 23, and 45-67 were rejected under the judicially created doctrine of obviousness-type double patenting over claims 11-17 of U.S. Patent 5,801,021. Claims 1, 6-13, 23, 45-53, 58-60, and 63 were rejected under the judicially created doctrine of obviousness-type double patenting over claims 1-9 of U.S. Patent 5,892,010.

Upon an indication of otherwise allowable subject matter, Applicants will provide a Terminal Disclaimer.

In view of the foregoing, Applicants believes all claims now pending in this application are in condition for an indication of allowable subject matter. Should the Examiner seek to maintain the rejections, Applicants request a telephone interview with the Examiner and the Examiner's supervisor.

If a telephone conference would expedite prosecution of this application, the Examiner is invited to telephone the undersigned at (510) 769-3513.

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Respectfully submitted,



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